EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Chainey Singleton on 12 March 2008.

The application has been amended as follows:

Please use the following version of the claims:

1. A method for preparing a native, acellular nerve tissue replacement comprising the steps of:

obtaining a nerve tissue;

soaking the nerve tissue for at least six hours in a solution comprising one or more sulfobetaines;

treating the nerve tissue in a mixture of one or more sulfobetaines and Triton X-200; and

washing the nerve tissue in one or more solutions of a buffered salt to remove excess detergent to form the native, acellular nerve tissue replacement with significantly reduced immunologic response relative to a nerve tissue graft made acellular by a freeze/thaw process or a decellularization process utilizing Triton X-100.

2. The method of claim 1, further comprising the step of storing the native, acellular nerve tissue replacement in a buffered salt solution until needed.

3. The method of claim 1, wherein the sulfobetaines have hydrophilic tails of 10 to 16 carbons.

4. The method of claim 1, further comprising the step of:

adhering one or more bioactive agents to the tissue replacement.

5-6. (cancelled)

7. The method of claim 4, wherein the one or more bioactive compounds comprises a drug.

8. (cancelled)

9. The method of claim 1, wherein the native, acellular nerve tissue replacement further comprises a structure selected from the group consisting of a tube, sheet, film, scaffold, and tissue transplant for delivery into the body.

10. The method of claim 1, wherein the sulfobetaine comprises SB- 16.

11. (cancelled)

12. The method of claim 1, wherein the step of washing the nerve tissue comprises one or more washes in a buffered salt solution comprising 100 mM sodium and 50 mM phosphate for at least 15 minutes each.

13. The method of claim 1, wherein the nerve tissue is harvested from a mammalian cadaver.

14. The method of claim 13, wherein the nerve tissue is cleaned of fat and blood after harvesting and rinsed two or more times in deionized distilled water.

15. A native, acellular nerve tissue replacement with significantly reduced immunologic response made by the method of claim 1.

16. A kit for tissue replacement comprising the native, acellular nerve tissue replacement with significantly reduced immunologic response of claim 15.

17. The kit of claim 16, wherein the native, acellular nerve tissue replacement further comprises a tube, a sheet, a film, a scaffold, or a nerve tissue transplant.

18. The kit of claim 17, wherein the native, acellular nerve tissue replacement further comprises a polymer, a bioactive compound or combinations thereof.

19. The kit of claim 17, further comprising a sheet of instructions for use of the native, acellular nerve tissue replacement.

20-40. (cancelled)

41. A method for preparing a native, acellular nerve tissue replacement comprising the steps of:

obtaining a nerve tissue;

soaking the nerve tissue for at least six hours in a solution comprising one or more sulfobetaines;

treating the nerve tissue in a mixture of one or more sulfobetaines and Triton X-200; and

washing the nerve tissue in one or more solutions of a buffered salt to remove excess detergent to form the native, acellular nerve tissue replacement, wherein the basal laminae and endoneurium layer substantially retain the native extracellular matrix structure.

42. (cancelled).

43. The method of claim 41, wherein the native, acellular nerve tissue replacement, when implanted, elicits a T-cell mediated immune response that is less than an immune response triggered by an allogeneic implant.

44. The method of claim 41, wherein the native, acellular nerve tissue replacement allows for higher axon density when implanted relative to a nerve tissue graft made acellular by a freeze/thaw process or a decellularization process utilizing Triton X-100.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651